IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MERIDIAN MEDICAL TECHNOLOGIES, INC., 1845 Craig Road St. Louis, Missouri 63146	)	
Plaintiff,	)	**Case No.** 4:23-cv-00566
vs.	)	
INTERNATIONAL BROTHERHOOD OF TEAMSTERS, CHAUFFEURS, WAREHOUSMEN AND HELPERS OF AMERICA, LOCAL UNION NO. 688, 4349 Woodson Road St. Louis, Missouri 63134	)	
Defendant.	)	

COMPLAINT TO VACATE ARBITRATION OPINION AND AWARD

COMES NOW, Plaintiff Meridian Medical Technologies, Inc., ("Plaintiff" or "Meridian"), by and through its undersigned counsel of record, and for its Complaint to Vacate Arbitration Opinion and Award ("Award") states as follows:

PARTIES

1. Plaintiff is a corporation organized under the laws of the State of Delaware, with its offices located in the County of St. Louis, State of Missouri, where it is engaging in the business of, among other things, the production of FDA-regulated pharmaceutical medical device combination products such as emergency use auto-injectors such as EpiPen and the antidote treatment nerve agent auto-injector ATNAA/DuoDote, used by the United States Armed Forces in the event of nerve agent poisoning in the field.

2. Plaintiff is an employer in an industry affecting commerce as defined in Sections 501(1) and (3) and 2(2) of the LMRA (29 U.S.C. §§ 142(1) and (3) and 152(2), and within the meaning of Section 301 thereof (29 U.S.C. §185).

3. Defendant International Brotherhood of Teamsters, Chauffeurs, Warehousemen and Helpers of America, Local Union No. 688 (hereinafter "Local Union No. 688" or the "Union"), is a labor organization representing employees in an industry affecting commerce, as defined in Sections 501(1) and (3) and 2(5) of the LMRA) (29 U.S.C. §§ 142(1) and (3) and 152(5)) and within the meaning of Section 301 thereof (29 U.S.C. §185), with offices in Saint Louis Missouri, where it acts as the exclusive collective bargaining representative for certain of Plaintiff's employees.

JURISDICTION

1. Plaintiff brings this action seeking to vacate and/or modify the Award issued by Mark W. Suardi on January 30, 2023.

2. This action arises under, and jurisdiction is conferred on this Court by virtue of, Section 301 of the Labor Management Relations Act, as amended 29 U.S.C. §185, hereinafter referred to as the LMRA, the United States Arbitration Act, 9 U.S.C. § *et seq*. and 28 U.S.C. §§ 1331, 1337.

3. This Honorable Court further has jurisdiction over this matter pursuant to 29 U.S.C. § 185(a), establishing in relevant part that suits arising under the LMRA "may be brought in any district court of the United States having jurisdiction over the parties, without respect to the amount in controversy or without regard to the citizenship of the parties."

4. This Honorable Court's jurisdiction is also established by 28 U.S.C. § 1331, because this action arises under the laws of the United States, to wit, the LMRA.

FACTS

5. Meridian manufactures FDA-regulated combination drug products, specifically EpiPen and ATNAA/DuoDote. Epipen is approved by the FDA and sold under US NDA XXXX. ATNAA/DuoDote is approved by the FDA and sold under US NDA XXX/US NDA XXXX.

6. As is relevant to the instant matter, Plaintiff and Defendant were parties to a collective bargaining agreement ("CBA") for the term of April 1, 2019, through March 31, 2022. A true and correct copy of the applicable CBA is attached hereto as **Exhibit A**.

A. Relevant CBA Terms

7. Article 9 of the CBA establishes Plaintiff's "management rights," which includes, but is not limited to, the right to "maintain efficiency, assign work and duties in accordance with the needs of [Plaintiff]" and "to impose discipline up to and including the act of discharge." [Exhibit A, pg. 6].

8. Article 19 of the CBA permits Plaintiff to discipline and terminate members of Defendant's bargaining unit for "just cause." [Exhibit A, pgs. 28-31].

9. Article 19 of the CBA also provides, in pertinent part, "no prior disciplinary action need be issued to an employee before they are suspended/discharged if the cause of such suspension/discharge is **dishonesty**, drunkenness, observed sleeping on the job while the employee is expected to be performing work, fighting on the job or otherwise violating the Company's Workplace Violence policy, **document altercation and/or falsification** (including signing for work that was not performed by/checked by the colleague(s) who signed for the work), three consecutive days of unreported absence (unless there are unusual/extenuating circumstances), possession and/or use of illegal drugs, willful or gross negligence or willful or

gross misconduct that results in loss of Employer property or product, refusal to obey a direct work order, and any other serious misconduct." (Emphasis Added) [Exhibit A, pgs. 28-31].

10. Article 20 of the CBA establishes a grievance and arbitration procedure ("Grievance Procedure") created to resolve differences between Plaintiff and Defendant regarding the terms of the CBA itself. [Exhibit A, pgs. 31-32].

11. The Grievance Procedure culminates in arbitration before an arbitrator appointed by the Federal Mediation and Conciliation Service ("FMCS"). [Exhibit A, pg. 32].

12. The CBA expressly establishes that "[t]he arbitrator shall have no authority to add to, detract from, or modify the provisions of [the CBA]." [Exhibit A, pg. 32].

13. Article 11, Section 2 of the CBA establishes:

> [Plaintiff] will provide a comprehensive training program. All training will consistent of written training, or online training, or training through observation, or hands-on training, or a combination of these as the particular training requires.
>
> At a minimum, the training will cover . . . Batch Records necessary for each member to complete his/her required tasks, based upon job classification . . . Training on updated SOPs and Batch Records will highlight the changes that have been made.

[Exhibit A, pg. 11]

14. Article 7 of the CBA establishes that all probationary employees (*i.e.*, new hires employed on a 90-day trial basis) must complete Batch Records training during their 90-day probationary period. [Exhibit A, pg. 5].

B. <u>The Grievance Procedure</u>

15. On June 2, 2020, Plaintiff terminated Cherie Miller ("Miller"), a member of the bargaining unit represented by Defendant in accordance with the language CBA.

16. Prior to her termination, Miller acted as a Qualified Trainer and Senior Technician on the third shift.

17. In this capacity, Miller was responsible for training probationary employees, including an employee named Kayla Harris ("Harris").

18. On or about March 27, 2020, Miller falsified company records and was dishonest in certifying that Harris had successfully completed five (5) training units.

19. An investigation by Plaintiff determined that Harris had not, in fact, completed the five (5) training units in question and that Plaintiff's records were falsified.

20. This investigation included a review of "batch records" and logbooks.

21. Accordingly, just cause for Miller's termination was established because Harris engaged in the falsification of Plaintiff's records and was dishonest in certifying that Harris had successfully completed five (5) training units.

22. Defendant filed a grievance protesting Miller's termination on June 7, 2020 (the "Grievance").

23. Plaintiff and Defendant were not able to resolve their dispute as to whether Plaintiff's decision to terminate Miller violated the terms of the CBA.

C. <u>The Arbitrator's Opinion and Award</u>

24. The Arbitrator was selected according to Article 20 of the CBA.

25. The Arbitrator held a hearing at Defendant's offices on January 18 and March 31, 2022.

26. The Arbitrator issued an Opinion and Award ("Award") on January 30, 2023. A true and correct copy of the Award is annexed hereto as **Exhibit B**.

27. The Award sustained the Grievance, directing that Ms. Miller be reinstated to her former position. [Exhibit B, pg. 16].

28. In sustaining the Grievance, the Arbitrator found that Plaintiff failed to meet its burden of proving that Harris' completion of Plaintiff''s training records "was intentionally fraudulent or falsified." [Exhibit B, pg. 16].

29. In making this finding, the Arbitrator ignored the language in the CBA stating that dishonesty is a terminable offense and added language to the CBA regarding "intentionally fraudulent."

COUNT I

The Award Violates Established and Strong Public Policy.

30. Plaintiff incorporates the facts set forth in Paragraphs 1 through 29 above as if set forth fully herein.

31. The Award recognizes that Plaintiff's production of ATNAA is "subject to stringent United States Food & Drug Administration ("FDA") requirements" and that training of probationary employees is thus of the utmost importance. [Exhibit B, pg. 3].

32. The Award further recognizes that the United States Armed Forces use ATNAA produced by Plaintiff, and the availability of safe, reliable, and effective ATNAA is a critical element of national security. [Exhibit B, pg. 3].

33. Common sense and basic notions of human decency mandate that all medical devices - - ***especially those used to protect the men and women of our Armed Forces in the event of use of chemical weapons*** - - be safe, reliable, and effective.

34. Over the course of the past one hundred and twenty-one (121) years, United States Congress has codified the principle that medical products must be safe, reliable, and effective no

less than thirteen (13) times, including: (a) the Biologics Control Act of 1902; (b) 21 U.S.C. § 1, *et seq.*; (c) the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*; (d) the 1951 Food, Drug, and Cosmetics Act Amendments, *Id.*; (e) the 1962 Food, Drug, and Cosmetics Act Amendments, *Id.*; (f) the Fair Packaging and Labeling Act, 15 U.S.C., § 1451, *et seq.*; (g) the Medical Device Regulation Act, 21 U.S.C. § 360c, *et seq.*; (h) the Prescription Drug Marketing Act, 21 U.S.C. § 331, *et seq.*; (i) the Dietary Supplement Health and Education Act, 21 U.S.C. § 301, *et seq.*; (j) the Food and Drug Administration Modernization Act, 29 U.S.C. § 301, *et seq.*; (k) the Public Health Security and Bioterrorism Preparedness and Response Act, 42 U.S.C. § 201, *et seq.*; (l) the Food and Drug Administration Amendments Act of 2007, 29 *U.S.C.* § 301, *et seq.*; and the (m) Food and Drug Administration Safety and Innovation Act, 29 *U.S.C.* § 301, *et seq.*

35. Accordingly, it is a violation of federal law to produce any drug or device that is adulterated because it:

> …[H]as been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health…is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure such drug meets the requirements [of federal law] as to safety….

21 *U.S.C.* § 351(a)(1).

36. The Food and Drug Administration ("FDA") has issued regulations setting specific standards for record-keeping and reporting for medical device producers. These regulations include 21 *C.F.R.* § 211.180, which establishes that:

> Any production, control, or distribution record that is required to be maintained in compliance with this party and is ***specifically associated with a batch of a drug product*** shall be retained for at least 1 year after the expiration date of the patch…[and] [w]ritten records required by this part shall be maintained so that data therein

> can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications of the manufacturing or control procedures….[which] shall include provisions for…[a] review of a representative number of batches, whether approved or rejected, and where applicable, records associated with the batch…

37. The FDA has also issued regulations establishing the importance of proper qualifications for all production employees. These regulations include 21 C.F.R. § 211.25, which establishes:

> Each person engaged in the manufacture, processing, packing, or holding of a drug product ***shall have the education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions***. ***Training shall be in the particular operations that the employee performs*** and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. ***Training in current good manufacturing practice shall be conducted by qualified individuals*** on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

38. Moreover, the FDA has promulgated severe penalties when an FDA-regulated manufacturer violates data compliance and record-keeping regulations. Data Integrity is defined by the FDA in its April 2016 "Draft Data Integrity and Compliance Guidance for Industry" as: "the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA)". Examples of CFR that require data integrity include 21 C.F.R. § 211 Current Good Manufacturing Practices for Finished Pharmaceuticals Part J Records and Reports, §211.180 General Requirements, §211.188 Batch Production and Control Records, and §211.194 Laboratory Records. Data violations can lead to FDA-issued Warning Letters, Withdrawl or suspension of the drug and/or device registration, injunction, as well as possible civil and criminal liability.

39. The Award expressly acknowledges the existence of the well-settled public policy of ensuring that all medical devices and substances are safe, reliable, and effective as follows and that only properly trained, competent employees should be engaged in the production of medical devices and substances:

> [Plaintiff] ***correctly argues that the nature of its business involves exacting standards of production*** which cannot be assured in the absence of properly trained employees….[and Plaintiff] is correct that the Learning Outcome Item Types and related verifications set forth in the proffered [records] constitute a reasonable exercise of managerial authority ***calculated to ensure that only fully qualified employees are…assigned to production duties***…

[Exhibit B, pg. 13]. *(emphasis supplied).*

40. The Award is in contravention of well-established public policy regarding ensuring that all drugs are produced safely, all documents related to the production of drugs are correct, and all employees are properly trained.

41. Thus, allowing a Meridian employee to violate FDA regulations and company policy and be reinstated clearly contradicts public policy. The fact that there was no penalty and the employee was reinstated exposes Meridian to the potential of such conduct being repeated by other employees.

42. While condoned by the Arbitrator, such behavior could lead to FDA penalties for falsifying documents, including product withdrawals or Meridian being shut down, and its life-saving medicines no longer available to the public. Therefore, the Arbitrator's Award undoubtedly contravenes well-established public policy against falsifying FDA-regulated documents.

43. The FDA regulates Plaintiff's operation, and the reinstatement of an employee who was dishonest and who falsified records places Plaintiff's business at risk and further violates well-established public policy.

44. Where an arbitrator issues an award that contravenes public policy, it may be properly vacated under the FAA. *W.M. Crittenden Ops., LLC v. United Food and Commercial Workers, Loc. Union No. 15*, 9 F.4th 732, 736-737 (8th Cir. 2021), *citing W.R. Grace & Co. v. Loc. Union 759, Intl. Union of United Rubber, Cork, Linoleum & Plastic Workers*, 461 U.S. 757, 766 (1983).

COUNT II

The Award Fails to Draw Its Essence From The CBA

45. Plaintiff incorporates the facts set forth in Paragraphs 1 through 40 above as if set forth fully herein.

46. In addition to the fact the Award issued by Arbitrator Suardi is in contravention of well-established public policy, the Award fails to draw its essence from the CBA and must be vacated for any of the following reasons:

a. In rendering his decision, Arbitrator Suardi exceeded his authority, including the authority granted to him under the terms of the parties' CBA;

b. The Arbitrator manifested infidelity to his duty under federal labor policy to draw the essence of the Award from the Collective Bargaining Agreement by disregarding the evidence and the express language in the CBA;

c. The Award is contrary to and disregards the express language and the plain, unambiguous meaning of the CBA in that it ignores that dishonesty is a terminable offense and,

instead, is premised on Plaintiff's failure to establish Miller engaged in intentional fraudulent behavior – language not contained in the CBA;

d. The Award is contrary to and disregards the express language and the plain, unambiguous meaning of the CBA in that it ignores that **document altercation and/or falsification** (including signing for work that was not performed by/checked by the colleague(s) who signed for the work), is a terminable offense and, instead, is premised on Plaintiff's failure to establish Miller engaged in intentional fraudulent behavior – language not contained in the CBA.

e. The Award is in contravention to the express language of the CBA stating "[t]he arbitrator shall have no authority to add to, detract from or modify the provisions of [the CBA] in that the Arbitrator added language to the CBA regarding "fraudulent behavior" and "intentionally fraudulent";

f. The Award is arbitrary and capricious insofar as the Arbitrator exceeded his power to interpret and apply the CBA by re-writing the CBA and imposing on the parties his own brand of industrial justice;

g. The Award fails to conform, or confine itself, to matters within the scope of the Arbitrator's jurisdiction and is arbitrary and capricious insofar as the Arbitrator exceeded his authority by re-writing the CBA and imposing on the parties his own brand of industrial justice by basing the Award on considerations of fairness and equity instead of the precise terms of the Agreement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that judgment be entered in its favor and that this Honorable Court enters an Order providing the following relief: (a) Vacatur of the Award, in its entirety; (b) a Declaration that the Award is Null, Void, and Unenforceable; and (c) granting such

other and further relief as this Court deems just, equitable, and proper. An appropriate hearing in this matter is requested.

Respectfully submitted this 1st day of May, 2023.

CONSTANGY, BROOKS, SMITH & PROPHETE, LLP
Attorneys for Plaintiff

By: /s/ Dean Kpere-Daibo
Dean Kpere-Daibo, #63010MO
Geoffrey M. Gilbert #43404 MO
680 Craig Road, Suite 400
St. Louis, Missouri 63141
Tel. (314) 338-3740
Email: dkdaibo@constangy.com
ggilbert@constangy.com